

# A RANDOMIZED COMPARATIVE DOUBLE BLIND STUDY TO COMPARE EFFICACY OF TWO DIFFERENT DOSES OF DEXMEDETOMIDINE (5mcg VS 10mcg) WHEN ADDED TO BUPIVACAINE AND FENTANYL COMBINATION IN SINGLE DOSE INTRATHECAL LABOUR ANALGESIA

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## Abstract

*Introduction - Perception of pain by a laboring female is a dynamic process that involves both peripheral and central mechanisms. The ideal technique for labor analgesia should provide rapid, effective, economical and safe pain relief for all stages of labor without compromising fetal vital physiology and wellbeing. It should not hamper the normal process of labor and should be flexible enough to convert to anaesthesia for urgent operative delivery or other intervention. Such an ideal technique would leave the mother awake, alert, and comfortable with preserved ability to ambulate and bear down throughout the labor. Hence the present study was designed to compare efficacy of two different doses of Dexmedetomidine (5mcg vs. 10mcg) when added to Bupivacaine and Fentanyl combination in single dose intrathecal labour analgesia.*

*Methodology - The study was done as the randomized controlled double blind study with 80 participants. A sample size 72 was calculated anticipating minimum of 20% decrease in VAS Score at the time of delivery considering significance of 95%  $\{\alpha 0.05\}$  and 80% Power of study  $\{\beta 0.2\}$ , thus we will be undertaking this study in 80 patients, which is clearly larger than 72 patients as calculated. Double blind randomization was done to allocate. Fulfilling the inclusion criteria, they were allocated into two equal groups of 40 patients using computerized block Randomization Technique.*

*Results - As intrathecal labor analgesia, also covers the duration of labour from 4-6cm cervical dilation till delivery of baby in maximum number of patients, it is a very good alternative to epidural analgesia in remote and far flung areas where epidural analgesia is not possible.*

*Keywords - labor analgesia, block randomization Technique, intrathecal labor analgesia*

## 1.0 Introduction

“Labor pains are one of the most distressing pain a human being may have to bear; there is no other circumstance where it is considered acceptable for a person to experience such severe pain, amenable to safe intervention, while under a physicians' care”. Hence option of labor analgesia should be given to all pregnant females: ASA and ACOG. According

to American Society of Anaesthesiology (ASA) “in absence of medical contraindication, maternal request is sufficient medical indication for pain relief during labor”[1].

The ideal technique for labor analgesia should provide rapid, effective, economical and safe pain relief for all stages of labor without compromising fetal vital physiology and wellbeing [2,3]. It should not hamper the normal process of labor and should be flexible enough to convert to anaesthesia for urgent operative delivery or other intervention. Such an ideal technique would leave the mother awake, alert, and comfortable with preserved ability to ambulate and bear down throughout the labor [4,5].

Parenteral opioids and sedatives are frequently used agents for women in labor in poor resource setting but are shown to have little or no effect on labor pain. Regional techniques are considered as gold standard for labor analgesia [6]. Types of regional techniques are caudal analgesia, lumbar epidural analgesia, and intrathecal analgesia and combined spinal epidural analgesia [7].

The use of adjuvant with bupivacaine started so that there could be effective and prolonged analgesia without concomitant motor blockade [8]. Various opioids such as morphine, fentanyl, sufentanyl either single or in combination of two have been used to increase the duration. The opioid receptors are densely concentrated at the level of substantia gelatinosa of the dorsal gray spinal matter. Intrathecal narcotics specifically bind to opioid receptors at this level and inhibit transmission of afferent visceral pain impulses [9, 10]. Since visceral pain is modulated at the level of dorsal horn, intrathecal narcotics provide adequate pain relief associated with first stage of labor but do not affect somatic pain associated with stretching of perineum during second stage of labor which can be managed by intrathecal low dose local anaesthetic such as bupivacaine. Hence combination of local anaesthesia & opioids or other adjuvants decreases complication, increases the efficacy & duration of labour analgesia [11, 12].

As very few studies have been done on ITA in laboring patients especially in this hilly state where epidural analgesia is not feasible in most of the institutes, ITA could be a boon to laboring patients who require labor analgesia in areas where either epidural analgesia cannot be undertaken or is contraindicated, hence we have decided to use ITA for laboring patients for evaluating its efficacy and effect on progress of labor. Hence the present study was designed to compare efficacy of two different doses of dexmedetomidine (5mcg vs 10mcg) when added to bupivacaine and fentanyl combination in single dose intrathecal labour analgesia. And to evaluate the efficacy and safety of different doses of dexmedetomidine (5 and 10 mcg) when added to bupivacaine and fentanyl combination for intrathecal labor analgesia. The total duration of analgesia of the two different doses were also evaluated. Two different doses of dexmedetomidine with regard to above two was compared [13].

## **2.0. Materials Methods**

### **2.1. Study details and sample size**

A randomized controlled double blind study was conducted under department of Anaesthesia after taking clearance from research ethics committee of the institution. Patients with the request for labor analgesia between the age 20-35yrs with the gestational age 37-42 weeks

who are having rimigravida singleton pregnancy with the dilatation 4-6 cms with Vertex presentation and ASA status I were selected for the study. The sample size 72 was calculated anticipating minimum of 20% decrease in VAS Score at the time of delivery considering significance of 95%  $\{\alpha 0.05\}$  and 80% Power of study  $\{\beta 0.2\}$ , thus we will be undertaking this study in 80 patients, which is clearly larger than 72 patients as calculated. Double blind randomization was done to allocate 80 parturients [14]. Fulfilling the inclusion criteria, they were allocated into two equal groups of 40 patients using computerized block Randomization Technique.

## **2.2. Methodology followed**

On admission to labour room detailed history and examination were undertaken by the obstetrician. After confirmation of inclusion criteria of the patient by the obstetrician the case was undertaken. Parturients with cervical dilatation of 4-6 cm were randomly allocated into two groups using sealed envelopes. An anaesthetist not involved in the study opened the already coded and sealed envelope for the parturients to pick from. The study solutions were prepared and coded by the anesthesiologist not involved in the study [15,16].

Ringer lactate infusion was started at normal maintenance rate before the procedure through already secured i.v cannula. All aseptic precautions were undertaken and the procedure was done in operation theatre. 3-L4 interspace was identified and 26-27 G spinal needle was introduced via median/Para median approach. Correct placement of spinal needle in subarachnoid space was confirmed by free flow of cerebrospinal fluid and coded drug was injected. Patient was kept in supine position for 10 min, and then allowed to ambulate with assistant [17].

## **2.3. Onset of analgesia (minutes)**

Time taken from injection of drug till decrease of VAS to less than or equal to 5 points during contraction; and it was treated as successful block. After injection of medication following data were obtained every 5 min for first 30 min, then every 30 minutes till delivery.

## **2.4. Quality of analgesia**

Quality of analgesia was assessed by VAS score ( $<5$ ), which was recorded during uterine contraction. After successful block if VAS increases to  $>5$ , it was considered as end point for duration of analgesia and alternate means of analgesia as per departmental protocol were provided.

## **2.5. Duration of analgesia**

Time taken for 2 segment regression from onset of analgesia; Sensory blockade was assessed by pinprick method. Level was recorded every 30 minutes till there is 2 segment regression which was taken as "Duration of analgesia". But if at any moment, VAS score increased to  $>5$  during labor, the duration of analgesia was taken from onset to that particular point.

## **2.6. Ambulation grading**

Effect on ambulation (EOA) will be categorized as having either

Grade I: No effect-able to walk properly or ambulate.

Grade II: Mild effect-feeling of numbness in the legs but not interfering with ability to walk or ambulate.

Grade III: Severe effect-Inability to walk or ambulate.

## 2.7. Maternal outcomes

Duration of 2<sup>nd</sup> stage: As noted by obstetrician. Urinary retention – need for catheterisation [Intermittent (number of times) / Continuous] was noted. Subsequently the details such as need for instrumentation, local infiltration for episiotomy: yes / no, and mode of delivery, Maternal satisfaction-assessed by 5 point scale.

## 2.8. Statistical analysis

After data assimilation codes were broken and appropriate statistical tests like paired t –test were undertaken using professional statistical software and results were brought up in light of statistical and clinical significance.

## 3.0. Results

### 3.1. Comparison of age (years) between group GD<sub>5</sub> and group GD<sub>10</sub>

Distribution of age was comparable between group GD5 and GD10 with majority of patients in the age group <=25 years (42.50% vs 45% respectively) followed by 26-30 years (42.50% vs 40% respectively) and very few patients were in the age group 31-35 years. (p value=0.971) Median (25th-75th percentile) of age (years) in group GD5 was 27(22.75-29) and group GD10 was 26(23.75-29) with no significant difference between them. It is shown in table 1,

**Table 1 - Comparison of age in years between group GD<sub>5</sub> and GD<sub>10</sub>**

Age(years)	Group GD <sub>5</sub> (n=40)	Group GD <sub>10</sub> (n=40)	Total	P value	Test performed
<=25	17 (42.50%)	18 (45%)	35 (43.75%)	0.971	Chi square test,0.059
26-30	17 (42.50%)	16 (40%)	33 (41.25%)		
31-35	6 (15%)	6 (15%)	12 (15%)		
Mean ± SD	26.32 ± 3.83	26.3 ± 3.4	26.31 ± 3.6	0.965	Mann Whitney test;795.5
Median(25th-75th percentile)	27(22.75-29)	26(23.75-29)	26.5(23-29)		
Range	20-35	21-33	20-35		

### 3.2. Comparison of period of gestation (weeks) between group GD5 and group GD10.

Mean  $\pm$  SD of period of gestation (weeks) in group GD5 was  $39.14 \pm 1.31$  and group GD10 was  $39.22 \pm 1.66$  with no significant difference between them. (p value=0.79). It is shown in table 2,

**Table 2- Comparison of period of gestation(weeks) between group GD5 and group GD10.**

Period of gestation(weeks)	Group GD5 (n=40)	Group GD10 (n=40)	Total	P value	Test performed
Mean $\pm$ SD	39.14 $\pm$ 1.31	39.22 $\pm$ 1.66	39.18 $\pm$ 1.49	0.79	t test;0.267
Median(25th-75th percentile)	39(38.143-40.036)	39.21(38-40.179)	39.07(38.143-40.143)		
Range	37-42	36.57-42	36.57-42		

### 3.3. Comparison of onset of analgesia (minutes) between group GD5 and group GD10

Median (25<sup>th</sup>-75<sup>th</sup> percentile) of onset Time of analgesia (minutes) in group GD10 [3(3-4)] was significantly decreased, as compared to group GD5 [4(3-5)] (p value=0.02).It is shown in table 3.

**Table 3 - Comparison of onset of analgesia (minutes) between group GD5 and group GD10**

Onset of analgesia(minutes)	Group GD5 (n=40)	Group GD10 (n=40)	Total	P value	Test performed
Mean $\pm$ SD	4.12 $\pm$ 1.59	3.3 $\pm$ 1.02	3.71 $\pm$ 1.39	0.02	Mann Whitney test;566
Median(25th-75th percentile)	4(3-5)	3(3-4)	3(3-5)		
Range	2-8	2-6	2-8		

### 3.4. Comparison of heart rate (per minute) between group GD5 and group GD10

Median(25th-75th percentile) of heart rate(per minute) at 10,15,20,25 & 30 minutes in group GD5 was 82(77.5-86.25), 82(76-88), 80(75-86), 80(75.5-88), 85(76-88.25) respectively which was significantly higher as compared to group GD5 (76(66-78), 67(65-76), 65(63-67), 65(60-66), 64(60.75-66.25)) respectively.(p value < 0.0001) No significant difference was seen in heart rate(per minute) at 0 minute, at 5 minutes between group GD5 and GD10.(p value >.05) HR in GD10 is more decreased as compared to GD5 . It is shown in table 4.

**Table 4 - Comparison of heart rate (per minute) between group GD5 and group GD10.**

Heart rate(per minute)	Group G <sub>D5</sub> (n=40)	Group G <sub>D10</sub> (n=40)	Total	P value	Test performed
<b>At 0 minute</b>					
Mean ± SD	90.2 ± 13.19	84.9 ± 9.42	87.55 ± 11.69	0.058	Mann Whitney test;604
Median(25th-75th percentile)	89(79-99)	88(78-89)	88(78-92)		
Range	64-120	65-110	64-120		
<b>At 5 minutes</b>					
Mean ± SD	83.5 ± 8.81	80.82 ± 8.35	82.16 ± 8.63	0.07	Mann Whitney test;613
Median(25th-75th percentile)	82(78-89)	81.5(76.75-88)	82(77-88)		
Range	62-102	66-98	62-102		
<b>At 10 minutes</b>					
Mean ± SD	81.12 ± 7.84	73.2 ± 7.87	77.16 ± 8.76	<.0001	Mann Whitney test;361.5
Median(25th-75th percentile)	82(77.5-86.25)	76(66-78)	78(70.5-84.25)		
Range	60-99	60-88	60-99		
<b>At 15 minutes</b>					
Mean ± SD	80.85 ± 8.48	68.8 ± 6.34	74.82 ± 9.6	<.0001	Mann Whitney test;220.5
Median(25th-75th percentile)	82(76-88)	67(65-76)	76(66.75-82.5)		
Range	62-98	60-86	60-98		
<b>At 20 minutes</b>					
Mean ± SD	79.72 ± 8.37	65.6 ± 6.24	72.66 ± 10.21	<.0001	Mann Whitney test;155
Median(25th-75th percentile)	80(75-86)	65(63-67)	72(65-80)		
Range	61-98	55-88	55-98		
<b>At 25 minutes</b>					
Mean ± SD	80.2 ± 8.05	64.2 ± 6.37	72.2 ± 10.81	<.0001	Mann Whitney test;108
Median(25th-75th percentile)	80(75.5-88)	65(60-66)	69(64.75-80.25)		
Range	64-90	54-87	54-90		
<b>At 30 minutes</b>					
Mean ± SD	82.75 ±	64.18 ±	73.46 ±	<.0001	Mann

	8.81	6.67	12.15	Whitney test;93
Median(25th-75th percentile)	85(76-88.25)	64(60.75-66.25)	72(64-86)	
Range	64-100	48-86	48-100	

### 3.5. Comparison of mean arterial pressure (mmHg) between group G<sub>D5</sub> and G<sub>D10</sub>

Median (25th-75th percentile) of mean arterial pressure (mmHg) at 15, 20, 25, 30 minutes in group GD10 was 66(65-75), 65(64-67), 65(64-66.25), 65(63.75-66) respectively. Which was significantly lower as compared to 69(66.75-75.25), 70(68.75-78), 74(68-78), 74(70-79.25) respectively in group GD5 (p value<.05). No significant difference was seen in mean arterial pressure (mmHg) at 0, 5 and 10 minutes between group GD5 and GD10 (p value >.05).

**Table 5 - Comparison of mean arterial pressure (mmHg) between group G<sub>D5</sub> and G<sub>D10</sub>**

Mean arterial pressure(mmHg)	Group G <sub>D5</sub> (n=40)	Group G <sub>D10</sub> (n=40)	Total	P value	Test performed
<b>At 0 minute</b>					
Mean ± SD	76.12 ± 2.2	75.75 ± 4.07	75.94 ± 3.25	0.655	Mann Whitney test;754.5
Median(25th-75th percentile)	76.5(74-78)	76(74.75-78)	76(74-78)		
Range	70-80	67-88	67-88		
<b>At 5 minutes</b>					
Mean ± SD	72.68 ± 7.27	73.3 ± 4.69	72.99 ± 6.09	0.427	Mann Whitney test;718
Median(25th-75th percentile)	70(67.75-77)	76(68-77)	74.5(68-77)		
Range	60-88	60-78	60-88		
<b>At 10 minutes</b>					
Mean ± SD	69.47 ± 6.22	69.82 ± 5.33	69.65 ± 5.76	0.896	Mann Whitney test;786.5
Median(25th-75th percentile)	69(65-72.5)	67.5(65-75)	69(65-74.25)		
Range	60-87	60-79	60-87		
<b>At 15 minutes</b>					
Mean ± SD	71.03 ± 6.57	68.47 ± 5.13	69.75 ± 5.99	0.014	Mann Whitney test;547
Median(25th-75th percentile)	69(66.75-75.25)	66(65-75)	67.5(65-75)		
Range	61-88	62-79	61-88		
<b>At 20 minutes</b>					
Mean ± SD	72.53 ± 6.13	66.28 ± 4.53	69.4 ± 6.21	<.0001	Mann Whitney test;301
Median(25th-75th percentile)	70(68.75-78)	65(64-67)	67.5(64-75.25)		
Range	64-84	60-79	60-84		
<b>At 25 minutes</b>					

Mean $\pm$ SD	73.62 $\pm$ 6.71	65.32 $\pm$ 3.45	69.47 $\pm$ 6.75	<.0001	Mann Whitney test;238.5
Median(25th-75th percentile)	74(68-78)	65(64-66.25)	67(64-74.25)		
Range	63-88	60-78	60-88		
<b>At 30 minutes</b>					
Mean $\pm$ SD	75.35 $\pm$ 6.58	64.8 $\pm$ 2.46	70.08 $\pm$ 7.25	<.0001	Mann Whitney test;75
Median(25th-75th percentile)	74(70-79.25)	65(63.75-66)	68(65-74)		
Range	60-90	58-69	58-90		

### 3.6. Comparison of visual analogue scale between group G<sub>D5</sub> and G<sub>D10</sub>

Median(25th-75th percentile) of visual analogue scale at 15,20,25,30,60,90,120,150,180 and at 210 minutes in group GD10 was (1(1-1.25), 1(1-1), 1(1-1), 1(0-1), 1(0.75-1), 1(1-1.25), 1.5(1-2), 3(2-3.25), 4(3-4), 5(4-6)) which was significantly lower as compared to group GD5 2(1-2), 2(1-2), 2(1-2), 2(1-2), 2(1-3), 3(2-4), 4.5(3-5), 5(5-5), 5(5-6), 6(5-6) respectively. (p value<.05) Median (25th-75th percentile) of visual analogue scale at 5 minutes in group GD10 was 2(2-3) which was significantly lower as compared to group GD5 with 3(2-4) (p value<.05)

No significant difference was seen in visual analogue scale at 0, 10 and at 240 minutes between group GD5 and GD10 (p value >.05). It is shown in table 6

**Table 6 - Comparison of visual analogue scale between group G<sub>D5</sub> and G<sub>D10</sub>**

Visual analogue scale	Group G <sub>D5</sub> (n=40)	Group G <sub>D10</sub> (n=40)	Total	P value	Test performed
<b>At 0 minute</b>					
Mean $\pm$ SD	6.52 $\pm$ 0.51	6.62 $\pm$ 1.13	6.58 $\pm$ 0.87	0.482	Mann Whitney test;732
Median(25th-75th percentile)	7(6-7)	7(6-7)	7(6-7)		
Range	6-7	4-9	4-9		
<b>At 5 minutes</b>					
Mean $\pm$ SD	2.62 $\pm$ 1.13	3.3 $\pm$ 1.14	2.96 $\pm$ 1.17	0.008	Mann Whitney test;535
Median(25th-75th percentile)	3(2-4)	2(2-3)	3(2-4)		
Range	1-6	1-5	1-6		
<b>At 10 minutes</b>					
Mean $\pm$ SD	2.12 $\pm$ 0.97	1.88 $\pm$ 0.72	2 $\pm$ 0.86	0.303	Mann Whitney test;702.5
Median(25th-75th percentile)	2(1.75-2.25)	2(1-2)	2(1-2)		
Range	1-5	1-4	1-5		
<b>At 15 minutes</b>					



Mean $\pm$ SD	1.98 $\pm$ 0.8	1.23 $\pm$ 0.58	1.6 $\pm$ 0.79	<.0001	Mann Whitney test;382.5
Median(25th-75th percentile)	2(1-2)	1(1-1.25)	1(1-2)		
Range	1-4	0-3	0-4		
<b>At 20 minutes</b>					
Mean $\pm$ SD	1.82 $\pm$ 0.75	0.95 $\pm$ 0.55	1.39 $\pm$ 0.79	<.0001	Mann Whitney test;316
Median(25th-75th percentile)	2(1-2)	1(1-1)	1(1-2)		
Range	1-4	0-2	0-4		
<b>At 25 minutes</b>					
Mean $\pm$ SD	1.78 $\pm$ 0.86	0.85 $\pm$ 0.53	1.31 $\pm$ 0.85	<.0001	Mann Whitney test;328.5
Median(25th-75th percentile)	2(1-2)	1(1-1)	1(1-2)		
Range	1-4	0-2	0-4		
<b>At 30 minutes</b>					
Mean $\pm$ SD	1.92 $\pm$ 0.92	0.8 $\pm$ 0.56	1.36 $\pm$ 0.94	<.0001	Mann Whitney test;264
Median(25th-75th percentile)	2(1-2)	1(0-1)	1(1-2)		
Range	1-4	0-2	0-4		
<b>At 60 minutes</b>					
Mean $\pm$ SD	2.2 $\pm$ 1.04	0.95 $\pm$ 0.71	1.58 $\pm$ 1.09	<.0001	Mann Whitney test;290
Median(25th-75th percentile)	2(1-3)	1(0.75-1)	1(1-2)		
Range	1-4	0-3	0-4		
<b>At 90 minutes</b>					
Mean $\pm$ SD	2.9 $\pm$ 1.37	1.18 $\pm$ 0.84	2.04 $\pm$ 1.43	<.0001	Mann Whitney test;247
Median(25th-75th percentile)	3(2-4)	1(1-1.25)	2(1-3)		
Range	1-6	0-3	0-6		
<b>At 120 minutes</b>					
Mean $\pm$ SD	4 $\pm$ 1.48	1.68 $\pm$ 0.97	2.84 $\pm$ 1.71	<.0001	Mann Whitney test;186
Median(25th-75th percentile)	4.5(3-5)	1.5(1-2)	3(1-4.25)		
Range	1-6	0-4	0-6		
<b>At 150 minutes</b>					
Mean $\pm$ SD	5.12 $\pm$ 0.72	2.55 $\pm$ 1.15	3.84 $\pm$ 1.61	<.0001	Mann Whitney test;31.5
Median(25th-75th percentile)	5(5-5)	3(2-3.25)	4(3-5)		
Range	2-7	0-4	0-7		
<b>At 180 minutes</b>					
Mean $\pm$ SD	5.42 $\pm$ 0.64	3.45 $\pm$ 1.15	4.44 $\pm$ 1.36	<.0001	Mann Whitney
Median(25th-75th percentile)	5(5-6)	4(3-4)	5(4-5)		

percentile)					test;102
Range	5-7	1-6	1-7		
<b>At 210 minutes</b>					
Mean $\pm$ SD	5.82 $\pm$ 0.78	4.7 $\pm$ 1.29	5.26 $\pm$ 1.2	0.0001	Mann Whitney test;400.5
Median(25th-75th percentile)	6(5-6)	5(4-6)	5(5-6)		
Range	5-8	2-7	2-8		
<b>At 240 minutes</b>					
Mean $\pm$ SD	6.05 $\pm$ 0.85	5.8 $\pm$ 0.72	5.92 $\pm$ 0.79	0.211	Mann Whitney test;681.5
Median(25th-75th percentile)	6(6-6)	6(5-6)	6(5-6)		
Range	5-9	5-7	5-9		

### 3.7 Comparison of maternal satisfaction between group G<sub>D5</sub> and G<sub>D10</sub>

Distribution of maternal satisfaction was comparable in group G<sub>D5</sub> and group G<sub>D10</sub> (Satisfied:- 42.50% vs 35%) and (Very satisfied:- 57.50% vs 65%) (p value = 0.491).It is shown in table 7.

**Table 7 - Comparison of maternal satisfaction between group G<sub>D5</sub> and G<sub>D10</sub>**

Maternal satisfaction	Group G <sub>D5</sub> (n=40)	Group G <sub>D10</sub> (n=40)	Total	P value	Test performed
Satisfied	17 (42.50%)	14 (35%)	31 (38.75%)	0.491	Chi square test,0.474
Very satisfied	23 (57.50%)	26 (65%)	49 (61.25%)		
Total	40 (100%)	40 (100%)	80 (100%)		

### 3.8 Comparison of will she receive labor analgesia in next pregnancy between group G<sub>D5</sub> and G<sub>D10</sub>

All the patients were satisfied and wanted to receive labor analgesia in the next pregnancy in both the groups.

**Table 8 - Comparison of will she receive labor analgesia in next pregnancy between group GD5 and GD10**

Will she receive labor analgesia in next pregnancy	Group G <sub>D5</sub> (n=40)	Group G <sub>D10</sub> (n=40)	Total	P value	Test performed
Yes	40 (100%)	40 (100%)	80 (100%)	No p value	-
Total	40 (100%)	40 (100%)	80 (100%)		

#### 4.0. Discussion

The present study was conducted to compare the efficacy of two different doses of Dexmedetomidine (5 mcg vs 10 mcg) when added to bupivacaine fentanyl combination for single dose intrathecal labor analgesia in the Department of Obstetrics and Gynecology, Kamla Nehru State Hospital for Mother and Child, Indira Gandhi Medical College, Shimla from 1<sup>st</sup> July, 2019 to 30<sup>th</sup> June, 2020.

80 parturients with uncomplicated pregnancy with a cervical dilatation of 4 to 6 cms were included in the study. They were randomised into two groups 40 of each using computer based randomisation. Group G<sub>D5</sub>(n=40)received single dose of 0.5 ml of 0.5% hyperbaric bupivacaine (2.5mg) with 0.5 ml fentanyl (25mcg) and 1 ml of Dexmedetomidine (5mcg) , total injectate 2 ml and group G<sub>D10</sub> (n=40) received single dose of 0.5 ml of 0.5% hyperbaric bupivacaine (2.5mg) with 0.5 ml fentanyl (25mcg) and 1 ml of Dexmedetomidine (10 mcg), total injectate 2 ml. The two groups were well matched in terms of age, parity, baseline vitals and mean cervical dilatation at the time of administration of labor analgesia. The data of the study were recorded in the record chart and results were analyzed using appropriate statistical tests (student t-test, Mann Whitney U test, Chi square test, Fishers exact test) as applicable [18,19]. Maternal vitals, onset of analgesia, visual analogue scale, time of two segment regression, maximum sensory block achieved, effect on analgesia and side effects such as nausea , vomiting, pruritis and urinary retention were compared between the groups G<sub>D5</sub> and G<sub>D10</sub>.

Intrathecal analgesia with higher dose of dexmedetomidine (10mcg) group G<sub>D10</sub> resulted in better pain relief as compared to the group G<sub>D5</sub>. Mean VAS score was  $2.12 \pm 0.97$  in group G<sub>D5</sub> and  $1.88 \pm 0.72$  in group G<sub>D10</sub>. The duration of analgesia was prolonged in the group G<sub>D10</sub> ( $216.75 \pm 19.79$  minutes) significantly, as compared to group G<sub>D5</sub> ( $132 \pm 24.31$  minutes). The duration of second stage of labor was comparable in both the groups (G<sub>D5</sub>:  $54.15 \pm 11.64$  and G<sub>D10</sub>  $54.62 \pm 11.34$  minutes). Intrathecal analgesia had no significant effect on maternal heart rate, mean arterial pressure, oxyhaemoglobin saturation, respiratory rate, and duration of labour and the outcome of labour. Intrathecal analgesia do not affect the mode of delivery and it was comparable in both the groups, in group G<sub>D5</sub>; 40 (100%) delivered by normal vaginal delivery, whereas in control group G<sub>D10</sub>; 37 (92.5%) delivered by normal vaginal delivery, 3 (7.5%) had instrumental delivery. All the parturient females in study groups delivered within the duration of intrathecal analgesia, therefore no other method of providing labor analgesia was required additionally. Intrathecal analgesia had mild effect on ambulation (grade II) in form of numbness in the lower limbs which got subsided in about 25 minutes in the group G<sub>D10</sub> ( 1.25%) Intrathecal opioids caused pruritis (6%), nausea and vomiting (18.75%) in some parturients and did not require any intervention [20,21].

#### 5.0. CONCLUSION

From our study we conclude that addition of 5µg & 10 µg of Dexmedetomidine as adjuvant to 2.5 mg of 0.5 % of hyperbaric bupivacaine and 25 µg of fentanyl for single shot intrathecal labour analgesia fasten the onset and prolong the duration of analgesia, but 10µg is more efficacious in pain relief without producing any significant hemodynamic changes and

side effects. As intrathecal labor analgesia, also covers the duration of labour from 4-6 cm cervical dilation till delivery of baby in maximum number of patients, it is a very good alternative to epidural analgesia in remote and far flung areas where epidural analgesia is not possible.

## References

1. Chestnut D, Bates J, Choi W. Continuous infusion epidural analgesia with lidocaine: Efficacy and influence during the second stage of labor. *International Journal of Gynecology & Obstetrics* 1988;26(1):167.
2. Alleemudder DI, Kuponiyi Y, Kuponiyi C, McGlennan A, Fountain S, Kasivisvanathan R. Analgesia for labour: *An Evidence-Based Insight For The Obstetrician. The Obstetrician & Gynaecologist*. 2015;17: 147–55.
3. Lynch L. Intrathecal drug delivery systems. *Continuing Education in Anaesthesia Critical Care & Pain*. 2014;14(1):27-31.
4. Kaur M. Adjuvants to local anesthetics: *A Combination Wisdom. Anesthesia: Essays And Researches*. 2010;4(2):122.
5. Rai A. Dexmedetomidine as an Additive to Spinal Anaesthesia in Orthopaedic Patients Undergoing Lower Limb Surgeries: A Randomized Clinical Trial Comparing Two Different Doses of Dexmedetomidine. *Journal Of Clinical And Diagnostic Research*. 2017; 11(4):9-13.
6. Stanley T. The Fentanyl Story. *The Journal of Pain*. 2014;15(12):1215-1226.
7. Farzi F, Mirmansouri A, NaderiNabi B, AtrkarRoushan Z, Ghazanfar Tehran S, NematollahiSani M et al. Comparing the Effect of Adding Fentanyl, Sufentanil, and Placebo with Intrathecal Bupivacaine on Duration of Analgesia and Complications of Spinal Anesthesia in Patients Undergoing Cesarean Section. *Anesthesiology and Pain Medicine*. 2017;7(5).
8. Clark V, Velde M, Fernando R. *Oxford Textbook Of Obstetric Anaesthesia*. 2016;1:368.
9. Safari F, Aminnejad R, Mohajerani S, Farivar F, Mottaghi K, Safdari H. Intrathecal Dexmedetomidine and Fentanyl as Adjuvant to Bupivacaine on Duration of Spinal Block in Addicted Patients. *Anesthesiology and Pain Medicine*. 2016;6(1):129-31.
10. Naaz S. Optimal Dose of Intrathecal Dexmedetomidine in Lower Abdominal Surgeries in Average Indian Adult. *Journal Of Clinical And Diagnostic Research*. 2016;.2016;10(4):9-13.
11. Herpolsheimer A, Schretenthaler J. The use of intrapartumintrathecal narcotic analgesia in a community-based hospital. *Obstetrics and gynecology*. 1994 Dec 1;84(6):931-6.

12. Lee BB, Kee WN, Hung VY, Wong EL. Combined spinal–epidural analgesia in labour: comparison of two doses of intrathecal bupivacaine with fentanyl. *British journal of anaesthesia*. 1999 Dec 1;83(6):868-71
13. Owen MD, Öz Saraç Ö, Şahin Ş, Uçkunkaya N, Kaplan N, Mağunaci I. Low-dose clonidine and neostigmine prolong the duration of intrathecal bupivacaine–fentanyl for labor analgesia. *The Journal of the American Society of Anesthesiologists*. 2000 Feb 1;92(2):361.
14. Viitanen H, Porthan L, Viitanen M, Heula AL, Heikkilä M. Postpartum neurologic symptoms following single-shot spinal block for labour analgesia. *Actaanaesthesiologicascandinavica*. 2005 Aug;49(7):1015-22.
15. Leslie et al Shukla U, Prabhakar T, Malhotra K, Srivastava D. Dexmedetomidine versus midazolam as adjuvants to intrathecal bupivacaine: A clinical comparison. *Journal of anaesthesiology, clinical pharmacology*. 2016 Apr;32(2):214.
16. Kanazi GE, Aouad MT, Jabbour-Khoury SI, Al Jazzar MD, Alameddine MM, Al-Yaman R, Bulbul M, Baraka AS. Effect of low-dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block. *Actaanaesthesiologicascandinavica*. 2006 Feb;50(2):222-7.
17. Kuczkowski KM, Chandra S. Maternal satisfaction with single-dose spinal analgesia for labor pain in Indonesia: a landmark study. *Journal of anesthesia*. 2008 Feb;22(1):55-8.
18. Minty RG, Kelly L, Minty A, Hammett DC. Single-dose intrathecal analgesia to control labour pain: Is it a useful alternative to epidural analgesia?. *Canadian family physician*. 2007 Mar 1;53(3):437-42.
19. Girgin NK, Gurbet A, Turker G, Aksu H, Gulhan N. Intrathecal morphine in anesthesia for cesarean delivery: dose-response relationship for combinations of low-dose intrathecal morphine and spinal bupivacaine. *Journal of clinical anesthesia*. 2008 May 1;20(3):180-5.
20. Shah A, Patel I, Gandhi R. Hemodynamic effects of intrathecal dexmedetomidine added to ropivacaine intraoperatively and for postoperative analgesia. *Int J Basic Clin Pharmacol* 2013;2:26-9.
21. Al-Mustafa MM, Abu-Halaweh SA, Aloweidi AS, Murshidi MM, Ammari BA, Awwad ZM, Al-Edwan GM, Ramsay MA. Effect of dexmedetomidine added to spinal bupivacaine for urological procedures. *Saudi Med J*. 2009 Mar 1;30(3):365-70.